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12  
13 UNITED STATES DISTRICT COURT  
14  
15 DISTRICT OF ARIZONA

16 In Re Bard IVC Filters Products  
17 Liability Litigation

18 No. MD-15-02641-PHX-DGC

19 Case No. 2:16-cv-00853-DGC

20 DEBRA MULKEY, an individual,

21 Plaintiff,  
22  
23 Plaintiff’s Controverting  
24 Statement of Facts in Opposition  
to Bard’s Motion for Summary  
Judgment as to Plaintiff Debra  
Mulkey’s Claims

25 v.

26 C.R. BARD, INC., a New Jersey  
27 corporation and BARD PERIPHERAL  
28 VASCULAR, an Arizona corporation,

Defendants.

1. Plaintiff Debra Mulkey received a Bard Eclipse® Filter (the “Filter”) on  
2 April 11, 2012, before she underwent bariatric surgery. (Ex. A, Plaintiff Fact Sheet of  
3 Plaintiff Debra Mulkey (hereinafter “PFS”), at §§ II.2(a), II.3).

4 **RESPONSE: Uncontroverted.**

5 2. The Filter is not sold directly to patients. (Ex. B, Eclipse Filter Instructions  
6 for Use (the “Eclipse IFU”) at page 1).

7 **RESPONSE: Controverted. Defendants fail to properly support their  
8 assertion of fact as required by Rule 56(c). The Eclipse IFU cited by  
9 Defendants states, “Caution: Federal (U.S.A.) law restricts this device  
10 to sale by or on the order of a physician.” The Eclipse IFU does not  
11 support Defendants’ contention that the Filter is not (or cannot be) sold  
12 directly to patients. Further, the Detailed Bill for Debra Mulkey (Ex.**

1                   **A) shows that Debra Mulkey was sold a Bard Vena Cava Filter System**  
2                   **directly by the medical provider and was charged \$2,031.25.**  
3                   **Defendants' SOF is silent as to the identity of the seller at issue.**

4                   3. Plaintiff's implanting physician, Dr. Roderick Tompkins, testified that he  
5                   placed the Filter in Plaintiff [REDACTED]  
6                   [REDACTED] (Ex. C, April 11, 2017 Dr. Roderick Tompkins Deposition Transcript  
7                   ("Tompkins Dep. Tr.") at 176:2 to 177:10).

8                   **RESPONSE: Controverted. The testimony cited by Defendants**  
9                   **actually states that Dr. Tompkins [REDACTED]**

10                   **[REDACTED] Def. Ex. C at 177:4-7. It is**  
11                   **unclear what a [REDACTED] means as used herein.**

12                   4. At the time Plaintiff received her Filter, [REDACTED]  
13                   [REDACTED]  
14                   [REDACTED] (Ex. D, Selected Plaintiff Medical Records).

15                   **RESPONSE: Uncontroverted as to the selected wording of the medical**  
16                   **history from the records, but controverted that this medical history**  
17                   **constitutes a material fact. There is no evidence in this case that**  
18                   **anything about Ms. Mulkey's prior medical history caused or**  
19                   **contributed to cause her filter to caudally migrate, tilt, become**  
20                   **irretrievable, perforate her vena cava, surrounding organs and spine,**  
21                   **and/or fracture. To the contrary, the evidence in this case is that the**  
22                   **defective design of Ms. Mulkey's Eclipse IVC filter caused her injuries**  
23                   **and complications.**

24                   5. Dr. Tompkins testified that before he placed the Filter, he had the IFU that  
25                   accompanied the Filter available to him to read. (Ex. C, Tompkins Dep. Tr. at 173:6-24.)

26                   **RESPONSE: Uncontroverted.**

27                   6. The Eclipse IFU applicable in April 2010 (when Plaintiff received her  
28                   Filter) included the following warnings:

29                   a. Under the bolded heading "**Potential Complications**," the Eclipse  
30                   IFU reads as follows:  
31                   • Movement, migration or tilt of the filter are known  
32                   complications of vena cava filters. Migration of filters to  
33                   the heart or lungs has been reported. There have also been  
34                   reports of caudal migration of the filter.

- Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques.
- Perforation or other acute or chronic damage of the IVC wall.

\* \* \*

- Filter Tilt

\* \* \*

All of the above complications have been associated with serious adverse events such as medical intervention and/or death. There have been reports of complications including death, associated with the use of vena cava filters in morbidly obese patients. The risk/benefit ratio of any of these complications should be weighed against the inherent risk/benefit ratio for a patient who is at risk of pulmonary embolism without intervention.

(Ex. B, Eclipse IFU).

b. Under the bolded “**Eclipse Filter Removal**” heading, the Eclipse IFU states in bolded language as follows:

**It is possible that complications such as those described in the “Warnings”, “Precautions,” or “Potential Complications” sections of this Instructions for Use may affect the recoverability of the device and result in the clinician’s decision to have the device remain permanently implanted.**

(Ex. B, Eclipse IFU).

**RESPONSE:** Uncontroverted that the referenced language is included in the applicable Eclipse IFU. Controverted that the cited language addresses or has any bearing on Plaintiff's causes of action for failure to warn. Plaintiff's failure to warn claim, among other bases, is that the language contained in the Eclipse IFU failed to convey the increased severity and frequency of the complications with that filter (and all of Bard's predecessor filters to the Eclipse).

26       7.     Dr. Tompkins testified that he would be speculating as to whether  
27 information and alleged facts told to him by Plaintiff's counsel would have altered his  
28 treatment decision for Plaintiff. Specifically, he testified as follows:

1           13    Q And it's important for you to rely on  
2           14    accurate or reliable information, isn't that  
3           15    right –

4           16    A Yes.

5           17    Q -- in making a decision as a medical  
6           18    doctor?

7           19    A Yes.

8           20    Q Okay. So -- so again, being shown a  
9           21    draft e-mail and asked if you had known, if you  
10           22    had known, would you have made a different  
11           23    decision, *you're really speculating, aren't you?*

12           24    MR. DeGEEFF: Object to the form.

13           25    A **Yes.**

14           1    Q Doctor, would you need much more  
15           2    information other than an e-mail or a couple of  
16           3    documents provided to you with testimony by  
17           4    counsel in making a decision whether you would use  
18           5    a product or not?

19           \* \* \*

20           8    A Can you restate that?

21           9    Q Sure.

22           10   Would you need information beyond  
23           11   documents taken out of context -- internal  
24           12   documents taken out of context to make a decision  
25           13   as to whether you would use a product or not?

26           14   MR. DeGEEFF: Object to form. Same  
27           15   objection.

28           16   A Yes.

(Ex. C, Tompkins Dep. Tr. 184:13 to 185:16).

1                   **RESPONSE: Controverted.** Defendants accurately cited the “cherry  
2 picked” testimony from pages 184:13 to 185:16 of Dr. Tompkins’  
3 deposition. However, Plaintiff controverts Defendants’ summary of Dr.  
4 Tompkins’ testimony and that it is consistent with the totality of his  
5 deposition testimony. Dr. Tompkins did not testify that he would be  
6 speculating as to whether the information and documents he was shown  
7 at his deposition would change his treatment decision. To the contrary,  
8 Dr. Tompkins testified as follows:

- 9                   • “I wouldn’t use the filter if I was aware that deaths were  
10                   occurring concurrently with me placing these filters.” (Ex. C,  
11                   Tompkins Dep. Tr. at 53:7-23).
- 12                   • If the Eclipse IFU had informed him of a significant difference in  
13                   the risk of migration over other filters, he wouldn’t have used  
14                   the filter. (Ex. C, Tompkins Dep. Tr. at 108:20 to 109:1). But  
15                   the Eclipse IFU did not inform Dr. Tompkins that the Eclipse  
16                   had a higher risk of movement, migration or tilt than any other  
17                   filter. (Ex. C, Tompkins Dep. Tr. at 108:3-9).
- 18                   • If the Eclipse had an increased risk of migration over other  
19                   filters, that is something he would have wanted to know and  
20                   something he would have taken into account in his risk benefit  
21                   analysis on whether to use the filter. (Ex. C, Tompkins Dep. Tr.  
22                   at 108:10-19).
- 23                   • If the Eclipse had an increased risk of migration over other  
24                   filters that would affect Dr. Tompkins’ prescribing habits and, if  
25                   it was a significant difference, he wouldn’t use the filter. (Ex. C,  
26                   Tompkins Dep. Tr. at 108:20 to 109:1).
- 27                   • If the IFU included pertinent warnings, that is something Dr.  
28                   Tompkins would pass on to his patients. (Ex. C, Tompkins Dep.  
Tr. at 106:7-10).
- There were risks and problems with Bard’s filters that Bard did  
not tell Dr. Tompkins about. (Ex. C, Tompkins Dep. Tr. at  
216:3-8).
- The Eclipse IFU did not inform Dr. Tompkins of an increased  
risk of movement, migration or tilt with Bard filters versus  
competitor filters. (Ex. C, Tompkins Dep. Tr. at 107:17-21).
- The Eclipse IFU did not inform Dr. Tompkins of an increased  
risk of movement, migration or tilt with Bard optional filters  
versus Bard permanent filters. (Ex. C, Tompkins Dep. Tr. at  
107:22 to 108:2).

1       8. Dr. Tompkins never testified that had he been given different information  
2 about the Eclipse Filter, it is probable that he would have decided against using the  
3 device.

4                   **RESPONSE: Controverted. Dr. Tompkins testified:**

- 5                   • **“I wouldn’t use the filter if I was aware that deaths were**  
6 **occurring concurrently with me placing these filters.” (Ex. C,**  
7 **Tompkins Dep. Tr. at 53:7-23).**
- 8                   • **If the Eclipse had an increased risk of migration over other**  
9 **filters, a significant difference that would affect Dr. Tompkins’**  
10 **prescribing habits and he wouldn’t use the filter. (Ex. C,**  
11 **Tompkins Dep. Tr. at 108:20 to 109:1).**
- 12                   • **If the Eclipse had an increased risk of migration over other**  
13 **filters, that is something that Dr. Tompkins would have wanted**  
14 **to know. (Ex. C, Tompkins Dep. Tr. at 108:10-15).**
- 15                   • **If the Eclipse had an increased risk of migration over other**  
16 **filters, that is something that Dr. Tompkins would have taken**  
17 **into account in his risk benefit analysis on whether to use the**  
18 **filter and it would have affected his prescribing habits. (Ex. C,**  
19 **Tompkins Dep. Tr. at 108:16-22).**
- 20                   • **He expected Bard to notify him immediately if it was aware of**  
21 **problems with the design of one of its filters that was causing**  
22 **complications and problems for patients, or if it was in the**  
23 **process of redesigning its filter to reduce complications. (Ex. C,**  
24 **Tompkins Dep. Tr. at 125:2-14). Dr. Tompkins wanted to know**  
25 **this information because it would help him decide whether he**  
26 **even wanted to use the filter. (Ex. C, Tompkins Dep. Tr. at**  
27 **125:2-18).**
- 28                   • **There were risks and problems with Bard’s filters that Bard did**  
29 **not tell Dr. Tompkins about. (Ex. C, Tompkins Dep. Tr. at**  
30 **216:3-8).**
- 31                   • **The Eclipse IFU did not inform Dr. Tompkins of an increased**  
32 **risk of movement, migration or tilt with Bard filters versus**  
33 **competitor filters. (Ex. C, Tompkins Dep. Tr. at 107:17-21).**
- 34                   • **The Eclipse IFU did not inform Dr. Tompkins of an increased**  
35 **risk of movement, migration or tilt with Bard optional filters**  
36 **versus Bard permanent filters. (Ex. C, Tompkins Dep. Tr. at**  
37 **107:22 to 108:2).**

1                   • **The Eclipse IFU did not inform Dr. Tompkins that the Eclipse**  
 2 **had a higher risk of movement, migration or tilt than any other**  
 3 **filter. (Ex. C, Tompkins Dep. Tr. at 108:3-9).**

4                   9. Dr. Tompkins testified that he relied on his experience, the experience of his  
 5 colleagues, and the applicable medical literature when he decided to implant an Eclipse  
 6 Filter in Ms. Mulkey. (Ex. C, Tompkins Dep. Tr. 202:7-22).

7                   **RESPONSE: Uncontroverted with clarification. The items listed by**  
 8 **Defendants in this SOF are accurate but do not include the entire basis**  
 9 **for Dr. Tompkins' decision to implant the Eclipse filter. For example,**  
 10 **prior to his decision to implant the Eclipse Filter in Ms. Mulkey, Dr.**  
 11 **Tompkins had seen the IFU for the Bard Eclipse filter, and it is his**  
 12 **practice to review the IFU for new devices prior to implanting them in**  
 13 **patients. (Ex. C, Tompkins Depo at 105:11-23). Additionally, he had**  
 14 **received information from Bard sales representatives who attended the**  
 15 **placement of filters in bariatric surgery patients by Dr. Tompkins to**  
 16 **provide him information if he had questions. (Ex. C, Tompkins Dep.**  
 17 **Tr. at 210:1-13; 105:15-18). This was an issue because there were risks**  
 18 **and problems with Bard's filters that it did not tell Dr. Tompkins**  
 19 **about. (Ex. C, Tompkins Dep. Tr. at 216:3-8). Dr. Tompkins wanted to**  
 20 **use the safest available IVC filter that would establish the goal of**  
 21 **stopping pulmonary embolisms. (Ex. C, Tompkins Dep. Tr. at 109:2-6).**  
 22 **At the time it was implanted, Dr. Tompkins did not expect the filter to**  
 23 **tilt and become irretrievable. (Ex. C, Tompkins Dep. Tr. at 97:25 –**  
 24 **98:3). At the time it was implanted, Dr. Tompkins did not expect the**  
 25 **filter to perforate Ms. Mulkey's vena cava or other organs in the future.**  
 26 **(Ex. C, Tompkins Dep. Tr. at 98:17-25). If Dr. Tompkins had expected**  
 27 **these issues to occur, he would not have used the filter. (Ex. C,**  
 28 **Tompkins Dep. Tr. at 99:1-5).**

10. Dr. Tompkins testified that he does not rely on information from medical  
 11 device manufacturers, such as Bard, when deciding which IVC filter he wanted to use.  
 12 Specifically, Dr. Tompkins testified as follows:

13                   19     Q     So -- so in -- in deciding which --  
 14                   20     which filter to use, do you rely on information  
 15                   21     from the manufacturer?  
 16                   22     A     No.  
 17                   (Ex. C, Tompkins Dep. Tr. 88:19-22).

1                   **RESPONSE: Controverted.** Plaintiff does not controvert that the  
 2 testimony from pages 88:19-22 is cited accurately. However, other  
 3 testimony from Dr. Tompkins proves this to be untrue. For example,  
 4 prior to his decision to implant the Eclipse Filter in Ms. Mulkey, Dr.  
 5 Tompkins had seen the IFU for the Bard Eclipse filter, and it is his  
 6 practice to review the IFU for new devices prior to implanting them in  
 7 patients. (Ex. C, Tompkins Depo at 105:11-23). Additionally, he had  
 8 received information from Bard sales representatives who attended the  
 9 placement of filters in bariatric surgery patients by Dr. Tompkins to  
 10 provide him information if he had questions. (Ex. C, Tompkins Dep.  
 11 Tr. at 210:1-13; 105:15-18). This was an issue because there were risks  
 12 and problems with Bard's filters that it did not tell Dr. Tompkins  
 13 about. (Ex. C, Tompkins Dep. Tr. at 216:3-8). Dr. Tompkins further  
 14 testified that he expected Bard to notify him immediately if it was aware  
 15 of problems with the design of one of its filters that was causing  
 16 complications and problems for patients, or if it was in the process of  
 17 redesigning its filter to reduce complications. (Ex. C, Tompkins Dep.  
 18 Tr. at 125:2-14). Dr. Tompkins wanted to know this information  
 19 because it would help him decide whether he even wanted to use the  
 20 filter. (Ex. C, Tompkins Dep. Tr. at 125:2-18).

21                   Dr. Tompkins also would have expected Bard to inform him of  
 22 problems with filters such as the Eclipse, and to provide him with  
 23 accurate and thorough information as it became aware of problems  
 24 with its filters. (Ex. C, Tompkins Dep. Tr. at 57:6-11; 157:22-25). All of  
 25 this was because Dr. Tompkins wanted to use the safest available IVC  
 26 filter that would establish the goal of stopping pulmonary embolisms.  
 (Ex. C, Tompkins Dep. Tr. at 109:2-6).

27                   11.       Dr. Tompkins testified he does not recall discussions with Bard's sales  
 28 representatives regarding the use of IVC filters in bariatric patients. (Ex. C, Tompkins  
 Dep. Tr. 55:10-13).

29                   **RESPONSE: Controverted.** Plaintiff does not controvert that the  
 30 deposition testimony is cited accurately. However, this testimony is in  
 31 dispute given other excerpts from Dr. Tompkins' deposition. For  
 32 example, Dr. Tompkins testified that Bard sales representatives were  
 33 present when he was performing IVC placements in bariatric patients  
 34 to provide him information if needed. ((Ex. C, Tompkins Dep. Tr. at  
 35 55:5-9; 210:1-13). Dr. Tompkins further testified that he does not  
 36 remember ever being told by any Bard sales representative that IVC  
 37 filters should not be used in bariatric patients. (Ex. C, Tompkins Dep.  
 38 Tr. at 55:14-17).

1       12. Dr. Tompkins testified that he discussed with Ms. Mulkey the risks and  
 2 benefits of IVC filter placement, and then obtained her informed consent before placing  
 3 the Filter. (Ex. C, Tompkins Dep. Tr. at 80:22 to 81:5; 86:3-11; 94:2-15).

4       **RESPONSE: Controverted. Dr. Tompkins testified that he did not**  
 5 **consent Ms. Mulkey to complications and injuries caused by failure of**  
 6 **the Eclipse filter; instead, he consented her only to certain risks**  
 7 **associated with the implant surgery itself. (Ex. C, Tompkins Dep. Tr.**  
 8 **at 80:22 – 86:2; 94:21 – 95:25). He further testified that he did not**  
 9 **inform Ms. Mulkey:**

- 10       • **About the risk of her IVC filter perforating the vena cava at any**  
       time after surgical insertion. (Ex. C, Tompkins Dep. Tr. at 82:3-8; 84:5-10).
- 11       • **That the IVC filter could in the future penetrate the inferior**  
       **vena cava and potentially surrounding organs. (Ex. C,**  
       **Tompkins Dep. Tr. at 84:11-15).**
- 12       • **Of the potential for the filter to migrate caudally following**  
       **surgical insertion. (Ex. C, Tompkins Dep. Tr. at 84:17-23).**
- 13       • **Of the potential for the filter to migrate cranially after**  
       **placement. (Ex. C, Tompkins Dep. Tr. at 84:24 to 85:3).**
- 14       • **About the risk of dislodgment of the filter at any time after**  
       **surgical insertion. (Ex. C, Tompkins Dep. Tr. at 82:9-25).**
- 15       • **About the potential irretrievability of the filter. (Ex. C,**  
       **Tompkins Dep. Tr. at 83: 3-5).**
- 16       • **About the potential that the IVC filter may perforate the vena**  
       **cava in the future. (Ex. C, Tompkins Dep. Tr. at 83:6-19).**

17       **Ms. Mulkey confirmed in her deposition that [REDACTED]**

18       **[REDACTED] (Ex. D, Mulkey Dep. Tr. at 183:13-**

19       **16). She did not believe that [REDACTED]**

20       **[REDACTED]. (Ex. D, Mulkey Dep. Tr. at**

21       **182:4-8). For example:**

- 22       • **Ms. Mulkey did not believe [REDACTED]**
- 23       **[REDACTED]. (Ex. D, Mulkey**
- 24       **Dep. Tr. at 182:9-13).**

- 1        • **Ms. Mulkey did not** [REDACTED]  
2        [REDACTED]. (Ex. D, Mulkey Dep. Tr. at 182:14-16; Ex. C,  
3        Tompkins Dep. Tr. at 83:20 to 84:4).
- 4        • **Ms. Mulkey did not** [REDACTED]. (Ex. D,  
5        Mulkey Dep. Tr. at 182:18-20).
- 6        • **Ms. Mulkey did not** [REDACTED]  
7        [REDACTED]. (Ex. D, Mulkey Dep. Tr. at 182:21-24).
- 8        • **Ms. Mulkey did not** [REDACTED]  
9        [REDACTED]. (Ex. D, Mulkey Dep. Tr. at 182:25 to 183:3).
- 10       • **Ms. Mulkey did not** [REDACTED]  
11       [REDACTED]. (Ex. D, Mulkey Dep. Tr. at 183:4-7).
- 12       • **Ms. Mulkey did not** [REDACTED] (Ex. D,  
13       Mulkey Dep. Tr. at 183:8-10).

12. On May 21, 2012, Plaintiff [REDACTED]  
13. [REDACTED] (Ex. D, Selected Plaintiff Medical Records).

14       **RESPONSE: Uncontroverted.**

15. On October 4, 2012, Ms. Mulkey underwent an unsuccessful percutaneous  
16 Filter removal procedure with Dr. Pho Nguyen. (Ex. D, Selected Plaintiff Medical  
17 Records).

18       **RESPONSE: Uncontroverted.**

19. The operative note from Plaintiff's October 4, 2012, unsuccessful removal  
20 procedure states that "[t]here is [] tilting of the IVC filter with the tip abutting the medial  
21 wall of the IVC," and the doctor was "unable to capture of the IVC filter due to the  
22 angulation of the IVC filter." (Ex. D, Selected Plaintiff Medical Records).

23       **RESPONSE: Uncontroverted.**

24. Plaintiff testified that on October 4, 2012, she understood Dr. Nguyen "was  
25 having some problems" trying to remove the Filter, that the Filter "had grown into the  
26 vein," that further attempts to remove the Filter could "caus[e] too much damage to my  
27 vein," and that, as a result, Dr. Nguyen would be unable to retrieve her Filter. (Ex. E,

1 February 8, 2017 Debra Mulkey Deposition Transcript (“Mulkey Dep. Tr.”) at 95:17 to  
2 97:1).

3 **RESPONSE: Controverted.** Plaintiff does not controvert that the  
4 testimony is accurately cited. Plaintiff contends that this testimony  
5 accurately summarizes Ms. Mulkey’s entire understanding at that time.  
Ms. Mulkey testified:

6 • She was not [REDACTED]. (Ex.  
7 D, Mulkey Dep. Tr. at 98:4-6).

8 • Dr. Nguyen did not e [REDACTED]  
9 [REDACTED]. (Ex. D, Mulkey Dep. Tr. at 180:11-13).

10 • She was not [REDACTED]  
11 [REDACTED]. (Ex. D, Mulkey Dep. Tr. at 113:12-20).  
In fact,  
12 [REDACTED] (Ex. D,  
13 Mulkey Dep. Tr. at 137:14-25). Dr. Tompkins confirmed he did  
14 not ever tell Ms. Mulkey that her IVC filter was defective, that  
Bard had injured her or caused her harm, or that her IVC filter  
was unsafe. (Ex. C, Tompkins Dep. Tr. at 115:19-116:3).

15 • At the time of her failed IVC removal in October of 2012, she:  
16 ○ did not [REDACTED]. (Ex. D, Mulkey Dep.  
17 Tr. at 179:21 – 180:1).  
18 ○ did not [REDACTED]  
19 [REDACTED]. (Ex. D, Mulkey Dep. Tr. at 180:2-5).  
20 ○ did not [REDACTED]  
21 [REDACTED]. (Ex. D, Mulkey  
Dep. Tr. at 180:5-10).

22 Ms. Mulkey testified [REDACTED]  
23 [REDACTED].

24 (Ex. D, Mulkey Dep. Tr. at 185:3-14).

25 17. Plaintiff testified that on October 4, 2012, she understood there was “some  
26 reason” why Dr. Nguyen was unable to remove her Filter. (Ex. E, Mulkey Dep. Tr. at  
99:7-10).

27 **RESPONSE: Controverted.** Plaintiff does not controvert that the  
28 testimony is accurately cited. Plaintiff contends that this testimony

1 accurately summarizes Ms. Mulkey's entire understanding at that time.  
2 Ms. Mulkey testified:

- 3 • She was not [REDACTED] (Ex.  
4 D, Mulkey Dep. Tr. at 98:4-6).
- 5 • Dr. Nguyen [REDACTED] (Ex. D, Mulkey Dep. Tr. at 180:11-13).
- 6 • She was not [REDACTED] (Ex. D, Mulkey Dep. Tr. at 113:12-20).  
7 In fact, Dr. Thompkins [REDACTED]  
8 [REDACTED]. (Ex. D,  
9 Mulkey Dep. Tr. at 137:14-25). Dr. Tompkins confirmed he did  
10 not ever tell Ms. Mulkey that her IVC filter was defective, that  
11 Bard had injured her or caused her harm, or that her IVC filter  
12 was unsafe. (Ex. C, Tompkins Dep. Tr. at 115:19-116:3).
- 13 • At the time of her failed IVC removal in October of 2012, she:
  - 14 ○ did not [REDACTED]. (Ex. D, Mulkey Dep.  
15 Tr. at 179:21 – 180:1).
  - 16 ○ did not [REDACTED] (Ex. D, Mulkey Dep. Tr. at 180:2-5).
  - 17 ○ did not [REDACTED] (Ex. D, Mulkey  
18 Dep. Tr. at 180:5-10).

19 Ms. Mulkey testified [REDACTED]  
20 [REDACTED]

(Ex. D, Mulkey Dep. Tr. at 185:3-14).

21 18. Plaintiff testified that on October 4, 2012, she knew she no longer needed  
22 her Filter. (Ex. E, Mulkey Dep. Tr. at 97:13-17).

23 **RESPONSE: Controverted. Plaintiff does not controvert that the**  
24 **testimony is accurately cited. Plaintiff contends that this testimony**  
25 **accurately summarizes Ms. Mulkey's entire understanding at that time.**  
Ms. Mulkey testified:

- 26 • She was not [REDACTED] e. (Ex.  
27 D, Mulkey Dep. Tr. at 98:4-6).

- 1     • **Dr. Nguyen** [REDACTED] (Ex. D, Mulkey Dep. Tr. at 180:11-13).
- 2
- 3     • **She was not** [REDACTED] (Ex. D, Mulkey Dep. Tr. at 113:12-20).
- 4     **In fact, Dr. Tompkins** [REDACTED] (Ex. D,
- 5     Mulkey Dep. Tr. at 137:14-25). Dr. Tompkins confirmed he did
- 6     not ever tell Ms. Mulkey that her IVC filter was defective, that
- 7     Bard had injured her or caused her harm, or that her IVC filter
- 8     was unsafe. (Ex. C, Tompkins Dep. Tr. at 115:19-116:3).
- 9
- 10    • **At the time of her failed IVC removal in October of 2012, she:**
- 11      ○ **did not** [REDACTED] (Ex. D, Mulkey Dep.
- 12        Tr. at 179:21 – 180:1).
- 13      ○ **did not** [REDACTED] (Ex. D, Mulkey Dep. Tr. at 180:2-5).
- 14      ○ **did not** [REDACTED] (Ex. D, Mulkey
- 15        Dep. Tr. at 180:5-10).

16     **Ms. Mulkey testified** [REDACTED]

17     [REDACTED] (Ex. D, Mulkey Dep. Tr. at 185:3-14).

18     19. Plaintiff testified that on October 4, 2012, she was “upset” that her filter  
could not be removed. (Ex. E, Mulkey Dep. Tr. at 185:3-9 (“[I]t upset me when I found  
out it [the Filter] couldn’t be removed.”)).

20

21     **RESPONSE: Controverted. Plaintiff does not controvert that the**  
22     **testimony is accurately cited. Plaintiff contends that this testimony**  
23     **accurately summarizes Ms. Mulkey’s entire understanding at that time.**  
24     **Ms. Mulkey testified:**

- 25     • **She was not** [REDACTED] (Ex.
- 26        D, Mulkey Dep. Tr. at 98:4-6).
- 27     • **Dr. Nguyen** [REDACTED] (Ex. D, Mulkey Dep. Tr. at 180:11-13).
- 28     • **She was not** [REDACTED] (Ex. D, Mulkey Dep. Tr. at 113:12-20).

## In fact, Dr. Tompkins

. (Ex. D, Mulkey Dep. Tr. at 137:14-25). Dr. Tompkins confirmed he did not ever tell Ms. Mulkey that her IVC filter was defective, that Bard had injured her or caused her harm, or that her IVC filter was unsafe. (Ex. C, Tompkins Dep. Tr. at 115:19-116:3).

- At the time of her failed IVC removal in October of 2012, she:
  - did not be [REDACTED] (Ex. D, Mulkey Dep. Tr. at 179:21 – 180:1).
  - did not [REDACTED] [REDACTED] (Ex. D, Mulkey Dep. Tr. at 180:2-5).
  - did not [REDACTED] [REDACTED] (Ex. D, Mulkey Dep. Tr. at 180:5-10).

**Ms. Mulkey testified**

(Ex. D, Mulkey Dep. Tr. at 185:3-14).

20. Plaintiff testified that the first time she experienced symptoms of any bodily injuries related to her Filter was on October 4, 2012, the day of her unsuccessful removal procedure. (Ex. E, Mulkey Dep. Tr. at 142:8-24).

**RESPONSE:** Controverted. Plaintiff does not controvert that the testimony is accurately cited. Plaintiff contends that this testimony accurately summarizes her entire understanding at that time. Ms. Mulkey did not realize at the time it was an injury or that anything was wrong with her filter. (Ex. D, Mulkey Dep. Tr. at 142:8-17 and 143: 14-22; Ex. E Plaintiff Fact Sheet of Plaintiff Debra Mulkey (hereinafter “PFS”), at Section II.13(b) on page 14). To the contrary, Ms. Mulkey testified:

- She was not [REDACTED] (Ex. D, Mulkey Dep. Tr. at 98:4-6).
- Dr. Nguyen [REDACTED] (Ex. D, Mulkey Dep. Tr. at 180:11-13).
- She was not [REDACTED] (Ex. D, Mulkey Dep. Tr. at 113:12-20).  
In fact, Dr. Thompkins [REDACTED]

1 [REDACTED] (Ex. D,  
2 Mulkey Dep. Tr. at 137:14-25). Dr. Tompkins confirmed he did  
3 not ever tell Ms. Mulkey that her IVC filter was defective, that  
4 Bard had injured her or caused her harm, or that her IVC filter  
was unsafe. (Ex. C, Tompkins Dep. Tr. at 115:19-116:3).

- 5 • At the time of her failed IVC removal in October of 2012, she:
  - 6 ○ did not [REDACTED]. (Ex. D, Mulkey Dep.  
Tr. at 179:21 – 180:1).
  - 7 ○ did not [REDACTED]  
[REDACTED] (Ex. D, Mulkey Dep. Tr. at 180:2-5).
  - 8 ○ did not [REDACTED]  
[REDACTED] (Ex. D, Mulkey  
Dep. Tr. at 180:5-10).

9  
10 Ms. Mulkey testified [REDACTED]  
11 [REDACTED].

12 (Ex. D, Mulkey Dep. Tr. at 185:3-14).

13 21. Plaintiff claims that “[i]n October 2015, I saw a commercial on TV that  
14 indicated that IVC filters were causing bodily injuries to people.” (Ex. A, PFS at §  
15 II.13(c)).

16  
17 **RESPONSE: Uncontroverted.**

18 22. Plaintiff testified that she never talked to any of her doctors about her IVC  
19 filter until December 2016. (Ex. E, Mulkey Dep. Tr. at 103:12 to 104:6).

20  
21 **RESPONSE: Uncontroverted.**

22 23. Plaintiff’s vascular and interventional radiologist expert, Dr. Darren Hurst,  
23 testified that Ms. Mulkey’s Filter could be removed via a complex percutaneous  
24 procedure. (Ex. F, July 21, 2017 Dr. Darren Hurst Deposition Transcript (“Hurst Dep.  
25 11 Tr.”) at 100:20 to 101:14).

26  
27 **RESPONSE: Objection, misstates the cited testimony. Controverted.**  
28 In the testimony cited by Defendants, Dr. Hurst actually testified that  
Ms. Mulkey’s filter could “potentially be removed percutaneously via a  
complex procedure.” (Ex. F, “Hurst Dep. Tr.” at 100:20-23). He

1 further testified that “each case is different, but [complex percutaneous  
 2 retrieval] would be worth trying.” (Ex. F, “Hurst Dep. Tr.” at 101:8-  
 3 101:14). Lastly, Dr. Hurst’s expert report clearly states: “Because the  
 4 filter could not be removed using the standard techniques and  
 5 equipment recommended by Bard, Ms. Mulkey will have to undergo  
 6 one or more additional removal procedures. Due to the significant risks  
 7 and potential complications associated with open, surgical removal of  
 8 the Eclipse Filter, it is reasonable for the removal of the filter to first be  
 9 attempted via advanced, complex percutaneous techniques. If this  
 10 retrieval is unsuccessful, surgical removal will be necessary.” (Ex. B,  
 11 **Hurst Report at pp. 12-13 ¶ (e)(i)(3)**).

12 24. Plaintiff’s cardiothoracic surgeon expert, Dr. Derek Muehrcke, testified that  
 13 Ms. Mulkey’s Filter could “likely” be removed via a complex percutaneous procedure.  
 14 (Ex. G, July 24, 2017 Dr. Derek Muehrcke Deposition Transcript (“Muehrcke Dep. Tr.”),  
 15 at 154:22 to 155:14).

16 **RESPONSE: Controverted.** Dr. Muehrcke merely testified that it was  
 17 “more likely” that Ms. Mulkey’s IVC would be able to be removed than  
 18 Ms. Kruse, another plaintiff. (Ex. G, Muehrcke Dep. Tr. at 155:2-9).  
 19 Dr. Muehrcke did not say it was “likely” Ms. Mulkey’s filter can be  
 20 removed via complex percutaneous procedure. *Id.* In fact, Dr.  
 21 Muehrcke’s expert report indicates, “The Eclipse Filter implanted in  
 22 Ms. Mulkey exhibited the following failure modes: caudal migration,  
 23 tilt, fracture, perforation of the vena cava, penetration of adjacent  
 24 organs and structures, and irretrievability. Due to these failures, the  
 25 Eclipse Filter cannot be removed percutaneously . . .” (Ex. H, Muehrcke  
 26 Report at p. 1). The report goes on to say “[B]ecause of the  
 27 unsuccessful endovascular removal procedure, and based on the degree  
 28 of tilt and perforation, a complex open vascular surgery to remove the  
 filter is now the most reasonable option to prevent further problems  
 from [Ms. Mulkey’s] device.” (Ex. H, Muehrcke Report at p. 7).

29 25. Plaintiff’s expert, Dr. Muehrcke, acknowledges that all IVC filters are  
 30 known to have potential complications, including filter fracture, migration, tilt, and  
 31 perforation. (Ex. G, Muehrcke Dep. Tr. at 55:22 to 57:9).

32 **RESPONSE: Controverted.** Dr. Muehrcke testified that some filters  
 33 are much less likely to have the potential complication of tilt. (Ex. G,  
 34 Muehrcke Dep. Tr. at 56:12-16). Dr. Muehrcke also testified that the  
 35 Bard G2 filter had an unacceptable caudal migration risk that Bard  
 36 had been aware of since late 2005, early 2006, resulting in an

1                   **unacceptable safety profile for the G2 filter. (Ex. G, Muehrcke Dep. Tr.**  
2                   **at 57:10-20).**

3                   26. Dr. Hurst testified that Ms. Mulkey's filter perforated her IVC, caudally  
4                   migrated, and fractured. (Ex. F, Hurst Dep. Tr., at 74:23 to 75:16).

5                   **RESPONSE: Uncontroverted with the clarification that these were not Ms.**  
6                   **Mulkey's only injuries that Dr. Hurst attributes to her Eclipse filter. For**  
7                   **example, Dr. Hurst's report also states that Ms. Mulkey's Eclipse filter**  
8                   **penetrated her adjacent organs and structures, as well as becoming**  
9                   **irretrievable. (Ex. B, Hurst Report at pp. 5-7, 12).**

10                  27. Plaintiff testified that she never received a patient card or brochure  
11                  regarding her IVC filter. (Ex. E, Mulkey Dep. Tr. at 67:11-18).

12                  **RESPONSE: Uncontroverted.**

13                  28. Plaintiff testified that she never asked for any information about her filter  
14                  before it was implanted. (Ex. E, Mulkey Dep. Tr. at 67:16-18).

15                  **RESPONSE: Controverted. Ms. Mulkey testified [REDACTED]**  
16                  **[REDACTED] (Ex. D, Mulkey Dep.**  
17                  **Tr. at 77:20-23; (Ex. C, Tompkins Dep. Tr. at 71:12-18). [REDACTED]**

18                  **[REDACTED] (Ex. D, Mulkey Dep. Tr. at 79:3-7). Ms.**  
19                  **Mulkey [REDACTED]**  
20                  **[REDACTED] (Ex. D, Mulkey Dep. Tr. at 88:5-16).**

21                  29. Plaintiff testified that she has never spoken to anyone at Bard. (Ex. E,  
22                  Mulkey Dep. Tr. at 167:11-13).

23                  **RESPONSE: Uncontroverted but immaterial.**

24                  30. Plaintiff testified that she has never visited Bard's website. (Ex. E,  
25                  Mulkey 28 Dep. Tr. at 69:24 to 70:1).

26                  **RESPONSE: Uncontroverted but immaterial.**

27                  31. Plaintiff testified that she did not know that Bard was the manufacturer of  
28                  her IVC filter until after she contacted her lawyer about her potential legal claim. (Ex. E,  
29                  Mulkey Dep. Tr. at 66:23 to 67:1).

30                  **RESPONSE: Uncontroverted but immaterial.**

1 RESPECTFULLY SUBMITTED this 2nd day of October 2017.  
2

3  
4 GALLAGHER & KENNEDY, P.A.  
5

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7

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14  
15 **CERTIFICATE OF SERVICE**  
16

17 I hereby certify that on this 2nd day of October 2017, I electronically transmitted  
18 the attached document to the Clerk's Office using the CM/ECF System for filing and  
19 transmittal of a Notice of Electronic Filing.  
20

21 /s/ Deborah Yanazzo  
22

23

24

25

26

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